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(Modified) PTO/SB/21 (6-98)
Approved for use through 09/30/2000. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM

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Total Number of Pages in This Submission

6

Application Number

09/687,593

Filing Date

October 13, 2000

First Named Inventor

Osamu Tetsu

Group Art Unit

1636

Examiner Name

Bronwen M. Loeb

Attorney Docket Number

305T-900500US

ENCLOSURES (check all that apply)

☐ Fee Transmittal Form

☐ Fee Attached

☒ Response to restriction requirement

☒ Extension of Time Request

☐ Express Abandonment Request

☐ Information Disclosure Statement

☐ Certified Copy of Priority Document(s)

☐ Response to Missing Parts/Incomplete Application

☐ Response to Missing Parts under 37 CFR 1.52 or 1.53

☐ Assignment Papers (for an Application)

☐ Drawing(s)

☐ Licensing-related Papers

☐ Petition Routing Slip (PTO/SB/69) and Accompanying Petition

☐ Petition to Convert to a Provisional Application

☐ Power of Attorney, Revocation Change of Correspondence Address

☐ Terminal Disclaimer

☐ Small Entity Statement

☐ Request for Refund

☐ After Allowance Communication to Group

☐ Appeal Communication to Board of Appeals and Interferences

☐ Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)

☐ Proprietary Information

☐ Status Letter

☒ Additional Enclosure(s) (please identify below):

receipt acknowledgment postcard

Authorization to Charge Deposit Account

Please charge Deposit Account No. 50-0893 for any additional fees associated with this paper or during the pendency of this application, including any extensions of time for consideration of the documents enclosed.

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name

Tom Hunter, Reg. No. 38,498, The Law Offices of Jonathan Alan Quine

Signature

Tom Hunter

Date

18 Sept 2001

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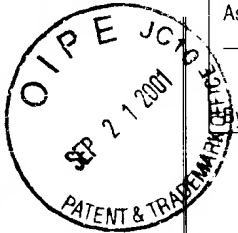
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

**OSAMU TETSU, KENICHI WAKITA, and
FRANK MCCORMICK**

Examiner: Bronwen M. Loeb, Ph.D.

Application No.: **09/687,593**

Art Unit: 1636

Filed: **10/13/2000**

For: **MAMMALIAN TWO-HYBRID
SYSTEM FOR SCREENING FOR
MODULATORS OF THE
ACCUMULATION OF METABOLIC
PRODUCTS**

**RESPONSE TO RESTRICTION
REQUIREMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated 07/30/2001, Applicants respectfully request reconsideration of the above-identified application in view of the following remarks. A petition to extend the period of response for one month(s) is enclosed.

In the 07/30/2001 Office Action the Examiner required restriction to one of the following groups under 35 U.S.C. §121:

- Group I: Claims 1-21, drawn to a method of screening for an agent that modulates the ability of a cell to accumulate or to degrade a metabolic product;
- Group II: Claims 22-39, drawn to a method of selectively expressing an effector gene in a cell that accumulates or degrades a metabolic product;
- Group III: Claims 40-59, drawn to a method of selectively killing a cell that accumulates a metabolic product; and

- Group IV: Claims 60-92, drawn to a recombinant cell and a nucleic acid; and
Group V: Claim 93, drawn to a compound that modulates the ability of a cell to accumulate or to degrade a metabolic product.

In response to this restriction requirement, Applicants provisionally elect Group I, claims 1-21 with traverse.

Applicants submit that restriction between Groups I, II, III, and IV is unnecessary. According to MPEP §803, the Examiner should examine all claims in an application, **even though they are directed to distinct inventions**, unless to do so would create a **serious burden**. In the instant case, the claims of Groups **I, II, and III** are all drawn to methods that utilize a two-hybrid system that exploits the interaction between a metabolic product and a ligand that binds to that metabolic product. The methods of Group I use this two-hybrid system with an effector gene to identify agents that modulate the ability of a cell to accumulate or to degrade the metabolic product. The methods of Group II use this two-hybrid system to selectively express the effector gene in a cell that accumulates or degrades the metabolic product. The methods of Group III use this two-hybrid system with an effector that is a cytotoxin to selectively kill a cell that accumulates or degrades the metabolic product.

A search for prior art relevant to this two-hybrid system is expected to identify any prior art, if such exists, relevant to all three methods. Thus examination of the methods of Groups I, II, and III entails no greater burden than examination of any one of these groups alone. Accordingly, there is serious burden entailed by examining Groups I-III together and Applicants respectfully request that the restriction between these groups be withdrawn.

Group IV is drawn to a cell comprising the two-hybrid system described above. Again, a search for prior art relevant to this two-hybrid system is expected to identify any prior art, if such exists, relevant to all to the cell as well as to the claimed methods. Thus examination of the methods of Groups I, II, III, and IV entails no greater burden than examination of any one of these groups alone. Thus, the restriction between Groups I, II, III, and IV should be withdrawn.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 337-7871.

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Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Tom Hunter", with a long horizontal flourish extending to the right.

Tom Hunter
Reg. No: 38,498